DEPARTMENT OF HEALTH AND HUMAN SERVICE
Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
FAX: 504-253-4566

September 13, 2000

WARNING LETTER NO. 2000-NOL-31

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Vincent Trinh
Owner
A Chau Sprouting Company
1728 Hancock Street
Gretna, Louisiana 70053

Dear Mr. Trinh:

We inspected your sprout growing facility, located at 1728 Hancock Street, Gretna, Louisiana, on June 5 and 7, 2000. During our inspection, we found that your facility is operating under seriously poor sanitary conditions and controls. The maintenance of your equipment and processing areas and the employee practices observed are inadequate to prevent seeds, sprouts, and processing water from becoming contaminated with filth or with pathogenic bacteria. Your sprouts are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act because they are being produced under insanitary conditions that may render them injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your facility.

On June 7, 2000, we issued to you a Form FDA 483, Inspectional Observations, which outlines conditions needing corrective action. Gross insanitary conditions, such as rodent excreta, live and dead roaches, a mold-like substance found throughout your facility, sprouts directly contacting the wet facility floor, and trays with finished product situated under a broken window in your operations room were documented and discussed with you. Additionally, you were observed pre-treating your mung bean and alfalfa seeds in a chlorine-water solution, which is not a recognized method of chemical pretreatment for sprout production. The enclosed guideline entitled, "Reducing Microbial Food Safety Hazards for Sprouted Seeds," states:

> "Antimicrobials are either pesticides, chemicals, or food additives, depending on where they are used. As such their use on seeds for sprouting must be approved by EPA or FDA. To find out what antimicrobials have been approved by EPA or FDA for use on seeds for sprouting, you may call (202) 418-3098."

The above list is not a complete list of conditions requiring corrective action. It is your responsibility to ensure that all of your operations are in compliance with applicable State and Federal requirements. Moreover, it is your responsibility to produce products that are safe for consumption. You should promptly correct the insanitary conditions and practices. FDA may initiate regulatory action without further notice, if you do not implement lasting corrections. You should seek advice from a recognized authority on the proper methods of preparing and handling raw seed and in-process and finished sprouts, as it is clear from our observations that your current methods are inadequate to prevent contamination of your finished sprout products with filth and/or pathogenic bacteria. Also, you may want to review Title 21, *Code of Federal Regulations*, Part 110, which sets forth Good Manufacturing Practice requirements used in manufacturing, packaging, and/or holding food for human consumption.

On the Form FDA 483, our investigator documented that you made a verbal commitment to correct the observed insanitary conditions and practices and to begin microbial testing of spent irrigation water used in the production of sprouts. Please notify this office in writing, within 15 working days of receipt of this letter, of the current status of your corrective actions and the specific steps you have taken to correct the noted conditions. Additionally, please include a detailed explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be directed to Rebecca A. Asente, Compliance Officer, at the address indicated on the letterhead above. If you have questions, you may contact Ms. Asente at (504) 253-4519.

Sincerely,

Nicole F. Hardin

Nicole F. Hardin
Acting District Director
New Orleans District

Enclosures: FDA-483
Guidance for Industry: "Reducing Microbial Food Safety Hazards for Sprouted Seeds" &
"Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"